UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION **This Document Relates to:** *MARK F. KRAMER and PEARL KRAMER, his wife, v. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS HOLDING USA, INC., PHILIPS RS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA HOLDING CORPORATION; USDNJ Case No. 2:22-cv-05869*	Master Docket: Misc. No. 21-1230 MDL No. 3014 **FIRST AMENDED COMPLAINT AND JURY DEMAND**

Plaintiffs, MARK F. KRAMER and PEARL KRAMER, his wife, who are citizens of New Jersey, by and through their counsel, allege as follows:

INTRODUCTION

1. Plaintiff, MARK F. KRAMER, brings this action for injuries suffered as a user of a Continuous Positive Airway Pressure (CPAP) device manufactured by the Defendants named herein. This device contains polyester-based polyurethane sound abatement foam ("PE-PUR Foam"), and other harmful substances, which results in the emission of certain carcinogenic chemicals and/or volatile organic compounds. Plaintiff, PEARL KRAMER, makes a derivative claim for loss of consortium arising from issues that are claimed by her lawful spouse, MARK F. KRAMER.

2. On April 26, 2021, Philips publicly announced that it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Royal Philips issued a recall ("Recall Notice") in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam. This was because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation. Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."

4. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue use of their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

5. In or about 2013, Mark F. Kramer obtained a Philips CPAP device through Community Surgical Supply. The CPAP device was a Philips Respironics System One REMstar PRO C-Flex+, Serial No. P09450809508B. Plaintiff used the CPAP device continuously and regularly every night from the date he received it until approximately September 2021.

6. In or about September 2021, Plaintiff discovered that Philips had recalled many CPAP devices when he came across an online article.

7. Soon after reading the online article and discovering the recalls, Plaintiff registered his CPAP device on the Philips website (see **Exhibit "A"**), and it was confirmed that Plaintiff's device was one of the devices recalled. As such, after consulting with his pulmonologist, Plaintiff immediately terminated use of the CPAP device.

8. Upon registering his CPAP device with Philips, Plaintiff was notified by Philips via telephone that they would place him on a list to provide him with a replacement CPAP device, as he continues to suffer with sleep apnea. Philips opened a claim for Plaintiff bearing claim number 2021082701348592.

9. In or about August 2022, Philips notified Plaintiff via telephone that they had secured a replacement CPAP device for him and would be sending him information on how to obtain his new CPAP device. To date, Plaintiff has not received his replacement device and continues to suffer with sleep apnea.

10. As a result of Plaintiff's usage of the Philips CPAP System One device, in or about December 2021, Mark Kramer was diagnosed with kidney cancer, resulting in the need for laparoscopic surgery in or about December 2021, and, ultimately, complete removal of his left kidney on May 4, 2022. Mr. Kramer must now undergo a cystoscopy every three (3) months for the foreseeable future.

11. Plaintiff has suffered and continues to suffer with this cancer, receiving continued treatments and follow ups, as well as cystoscopies every three (3) months, resulting in associated pain, suffering, and emotional distress.

12. Plaintiff was and still is caused to suffer serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional adverse health consequences. He also has increased out of pocket costs for medical treatment, medications, and supplies on an ongoing basis.

13. Consequently, Plaintiff seeks compensatory damages as a result of his use of the Philips CPAP device.

14. There were no materials accompanying Plaintiff's System One CPAP device (herein "System One device" or "Recalled Device") which contained any language or warnings of health risks associated with use of the device, such as irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects.

15. Without knowing the health risks associated with use of the Recalled Device, Plaintiff used the Recalled Device as prescribed by his physicians to treat his sleep apnea.

THE PARTIES

16. Plaintiffs, MARK F. KRAMER and PEARL KRAMER, (herein collectively and individually "Plaintiff" or "Kramer") reside at 49 Locust Drive, Morris Plains, New Jersey, and are citizens of the State of New Jersey, residing in Morris County. Plaintiff, PEARL KRAMER, is the lawful wedded spouse of Plaintiff, MARK F. KRAMER.

17. Defendant, KONINKLIJKE PHILIPS N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America, LLC and Philips RS North America, LLC.

18. Defendant, PHILIPS NORTH AMERICA LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America.

19. Defendant, PHILIPS HOLDING USA, INC. (“PHUSA”), is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent, Corporation Service Company, at 1201 Hays Street, Tallahassee, FL 32301-2525.

20. Defendant, PHILIPS RS NORTH AMERICA LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS and is a wholly-owned subsidiary of Royal Philips.

21. Defendant, PHILIPS RS NORTH AMERICA HOLDING CORPORATION (“RS Holding”) is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, RS Holding is a citizen of Massachusetts and Delaware.

22. Philips RS formerly operated under the business name Respironics. Royal Philips acquired Respironics in 2008.

23. Royal Philips, Philips NA, PHUSA, Philips RS, and RS Holding are hereinafter collectively referred to as “Philips” or “Defendants.”

JURISDICTION AND VENUE

24. Jurisdiction of this Court is based on diversity of citizenship and the amount in controversy is in excess of the jurisdictional limit of $75,000.00. 28 U.S.C. Section 1332(a)(1). Venue is proper in this judicial District pursuant to 28 U.S.C. 6 1391(b) and (c). This Court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process because Defendants conduct substantial business in this District, the events giving rise to Plaintiff's claims arise out of and relate to defendant's contacts with this

District. Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in this forum State. The unlawful acts of defendants have been directed at, targeted to, and effectively caused injury to persons residing in, located in or doing business in this District.

25. Venue is proper in this District pursuant to 18 U.S.C. 6 1965(b).

NATURE OF CASE

26. This is a lawsuit seeking judgment against Defendants, KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS HOLDING USA, INC., PHILIPS RS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA HOLDING CORPORATION (herein collectively "Philips" or "Defendants") for personal injuries sustained from Defendants' unreasonable dangerous product, the System One device manufactured and sold by Defendants, as well as various common law and statutory causes of action resulting from the purchase of this dangerous machine.

27. At all times relevant hereto, Defendants designed, created, manufactured, assembled, produced, tested, packaged, labeled, marketed, advertised, promoted, supplied, and/or sold the System One device.

28. Philips manufacturers and sells medical equipment products. These products include Continuous Positive Airway Pressure ("CPAP") as well as Bi-level Positive Airway Pressure ("BI-PAP") machines, which are used in the treatment of sleep apnea, and ventilators, which treat respiratory failure.

29. On June 14, 2021, Philips announced a recall of many of its CPAP/BI-PAP machines and its ventilators because they suffer from a defect that could result in serious injury, permanent impairment, and may even be life-threatening.

30. According to Philips, the PE-PUR foam, which is used in the devices to reduce noise, can deteriorate over time, causing the foam to break down. When the foam breaks down, small foam particles and gases can be inhaled or ingested through the use of the devices which assist patients with respiration. The foam may emit volatile organic compounds which, when inhaled, can result in serious adverse health effects, including cancer.

31. Philips reports that lab analysis of the degraded foam reveals the presence of harmful chemicals, including Toluene Diamine ("TOA"), Toluene Diisocyanate ("TOI"), and Diethylene Glycol ("DEG").

32. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devises (extending from the device outlet, humidifier, tubing and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure, and sinus infection from users of this device.

33. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include irritation (skin, eye and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these devices include headache/dizziness, irritation (of the eyes, nose, respiratory tract and/or skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

34. The design of BIPAP and CPAP devices results in air being forced past potentially degraded PE-PUR foam before it is pumped into the patient's airway, thus exposing users to these toxins.

FACTUAL ALLEGATIONS

35. CPAP and BI-PAP machines are medical devices used to treat sleep apnea, which is a respiratory condition characterized by interruptions in breathing, repeatedly throughout an individual's sleep cycle, referred to as apneas.

36. The apneas occur when the muscles in the back of the patient's throat relax and cause a mechanical disruption of breathing. Symptoms of this condition include excessive daytime sleepiness, episodes of stopped breathing during sleep, sudden awakenings accompanied by gasping or choking, high blood pressure, and mood changes due to lack of sleep. Severe episodes of sleep apnea can lead to hypertension, heart attack, or stroke. It is estimated that this condition affects between two (2) and nine (9) percent of adults in the United States.

37. A widely used nonsurgical treatment for sleep apnea is continuous positive airway pressure therapy through the use of a BI-PAP or CPAP machine. This device delivers a constant flow of air through a mask that is placed over the nose and mouth of the patient, which assists in maintaining steady breathing while sleeping.

38. BI-PAP machines are similar to CPAP machines that treat sleep apnea. However, unlike CPAP machines, BI-PAP machines use two different pressures to mimic inhaling and exhaling, rather than the single continuous level of pressurized air delivered by a CPAP device.

39. CPAP and BI-PAP machines both consist of a main unit which connects to a facemask via an air hose. They are typically prescribed for nightly use in order to treat the sleep apnea. Certain CPAP machines, such as the one used by Plaintiff, also contain a humidifier that serves to humidify and warm the air that is breathed through the attached hose.

40. Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BI-PAP devices, as well as ventilator devices under its "Sleep and Respiratory Care" brands.

41. Defendants obtained Food and Drug Administration ("FDA") approval to market the Recalled Devices, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. This provision permits marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

42. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by FDA.

43. Clearance for sale under the 510(k) process does not equate to "FDA approval" of the cleared device. In 2012, at the request of the FDA, the National Institute of Health ("NIH") conducted a thorough review of the 5l0(k) process and concluded this process was not intended to ensure the safety of medical devices, stating:

> The 5l0(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 5l0(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to a previously cleared device.

44. NIH explained, "[t]he assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable' assurance of safety and effectiveness."[1]

45. Philips utilized the 510(k) clearance process for the Recalled Devices, including Plaintiff's device.

[1] Institute of Medicine (U.S.) Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process, Medical Devices and the Public's Health 189 (Institute of Medicine, 2011).

THE RECALL NOTICE

46. On April 26, 2021, Philips disclosed in its Quarterly Report for Ql 2021 that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used and installed into several CPAP and other types of respirators to minimize noise, posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone and certain environmental conditions involving high humidity and temperature.[2]

47. Thereafter, on June 14, 2021, Philips issued a recall notification for specific affected devices.[3]

48. According to Philips, this PE-PUR foam can deteriorate over time, causing it to break down into foam particles and gasses which can be inhaled or ingested through the use of the CPAP/BI-PAP devices. The foam may emit volatile organic compounds which, when inhaled, can result in a wide range of potential patient impact, from transient injuries, worsening symptoms, or serious life-threatening injury.

49. The recall notice included the following potential heath injuries: "Particulate exposure can cause headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting and possible toxic and carcinogenic effects."[4] A copy of the recall notice is attached as **Exhibit "B."**

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[2] *First Quarter Results,* PHILIPS (Apr. 26, 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf

[3] *Medical Device recall notification (U.S. only) I field safety notice (International Markets),* PHILIPS RESPIRONICS *June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-updat#section

[4] Philips issues recall notification, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips- issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html.

50. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including: Toluene Diamine, Toluene Diisocyanate, Diethlene glycol."[5] In this same report, Philips also disclosed that through testing performed by and for Philips, the presence Volatile Organic Compounds (VOCs) was confirmed stating: "VOCs emitted as gases from the foam included in the [affected devices] and may have short and long-term adverse health effects. Standard testing identified two compounds of certain may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following: Dimethyl Diazine and Phennol, 2,6-bs (1,1- dimethylethyl)-4-(1-methlypropyl)-."

51. Philips disclosed that an estimated number of "between 3 million and 4 million" devices are subject to the recall.

52. On July 8, 2021, Philips released clinical information based on their own testing of the affected devices, stating that, "According to the analysis performed by Philips, the majority of particulates are of a size (≥8 μm)… "Smaller particulates (,1-3 μm) are capable of diffusing into deep lung tissue and deposit into the alveoli" "During testing performed by an outside laboratory on lab degraded foam. The smallest particulate size identified was 2.69 μm."

53. The Environmental Protection Agency (EPA) has indicated that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases.

[5] Sleep and Respiratory Care update, Clinical information for physicians, PHILIPS (June 14, 2021), Reuters.com/business/healthcare-pharmaceuticals/Philips-recalls-some-3-4million-CPAP-ventilator-machines-due-to-foam-part-2021-06-121/

54. On July 29, 2021, the FDA classified the recall as a Class I recall, the most serious type of recall, and stated, "Use of these devices may cause serious injuries or death."

55. Philips instructed users of the recalled CPAP and BI- PAP devices to, "Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks." Philips instructed users of the recalled ventilator devices to, "NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."

56. The devices subject to the recall were listed in the June 14, 2021 recall notification. The list of affected Philips devices includes 18 CPAP, BI-PAP, and Ventilator type devices as follows:

a. Type: Continuous Ventilator, Minimum Ventilatory Support, Facility Use
    i. Model: E30 (Emergency Use Authorization
b. Type: Continuous Ventilator, Non-Life Supporting
    i. Model: DreamStation, ASV
    ii. Model: DreamStation, ST, AVAPS
    iii. Model: System One, ASV4
    iv. Model: C Series, ASV, S/T, AVAPS
    v. Model: OmniLab Advanced Plus, In-lab Titration Device
c. Type: Non-Continuous Ventilator
    i. Model: System One (Q series)
    ii. Model: DreamStation
    iii. Model: DreamStation GO
    iv. Model: Dorma 400, 500

v. Model: REMStar SE Auto

d. Type: Mechanical Ventilators

i. Model: Trilogy 100

ii. Model: Trilogy 200

iii. Model: Garbin Plus, Aeris, LifeVent

e. Type: Continuous Ventilator, Minimum Ventilatory Support, Facility Use

i. Model: A-Series BIPAP Hybrid A30

ii. Model: A-Series BIPAP V30 Auto

f. Type: Continuous Ventilator, Non-Life Supporting

i. Model: A-Series BIPAP A40

ii. Model: A-Series BIPAP A30

57. Prior to issuing its regulatory update on April 26, 2021, Philips failed to disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam may off-gas or degrade upon use. Indeed, Philips did not disclose any health risks associated with use of its BI-PAP, CPAP, or ventilators.

58. Defendants have not disclosed when they first received reports or discovered from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

59. These reports from users clearly made Defendants aware of the off-gassing and degradation problems from the PE-PUR Foam at some point prior to the recall, yet Defendants continued to manufacture and sell these devices with such awareness. Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

TOLLING AND ESTOPPEL

I. DISCOVERY RULE TOLLING

60. Plaintiff had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Device.

61. Plaintiff, through the exercise of reasonable care, could not have discovered the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

62. For these reasons, all applicable statutes of limitation should be tolled by the discovery rule with respect to claims asserted by Plaintiff.

II. FRAUDULENT CONCEALMENT TOLLING

63. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff.

64. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault or lack of diligence on Plaintiff's part and could not have reasonably discovered Defendants' conduct. For these reasons, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

CAUSES OF ACTION

COUNT I

PRODUCT LIABILITY

DESIGN DEFECT (NJSA 2a:58C-1, et seq.)

65. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

66. The recalled machines, including the Philips System One CPAP machine used by Plaintiff Mark Kramer, was not reasonably safe for its intended uses and was defectively designed. These design defects include, but are not limited to:

a. the use of polyurethane PE-PUR sound abatement foam in the Recalled Devices, including the Philips System One CPAP machine and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Failing to design the Recalled Devices, as well as the Philips System One CPAP machine so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

c. Including in the design of the Recalled Machines, as well as the Philips System One CPAP device, flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung and cancer of the larynx, as well as other injuries;

d. Failing to use alternatively available sound abatement materials and/or foams in the Recalled Devices, as well as the Philips System One CPAP device

machine, such as plastic, silicone, or rubber, which would not break down, flake off and infiltrate the device's air pathway while the user is sleeping;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Recalled Devices, including the Philips System One CPAP device.

67. The use of the Recalled Devices, as well as Plaintiff's use of the Philips System One CPAP device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

68. The Recalled Devices, including the Philips System One CPAP machine used by Plaintiff, were defective in their design in that they failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

69. The Recalled Devices, including the Philips System One CPAP device used by Plaintiff, are further defective in that (a) the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, (b) there were feasible, safer alternative designs known to Defendants at the time of manufacture, (c) the financial costs of an improved design was minor, and (d) there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

70. Defendants, and each of them, knew that the Recalled Devices, including the Plaintiff's System One machine, and the component parts of these BI-PAP and CPAP machines, would be purchased and used without inspection for defects in the design of the machine or its masks/attachments.

71. The recalled machines, including the Plaintiff's System One machine, and the component parts of these CPAP and BI-PAP machines were defective when they left the control of each of these Defendants.

72. As a direct and proximate result of the recalled machines, including Plaintiff's defective Philips System One CPAP device aforementioned defects, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, expenses associated with medical services, lost income, and other damages.

73. Defendants are strictly liable to Plaintiff, Mark Kramer, for designing, manufacturing, marketing, labeling, packaging, and selling the Recalled Devices, including Plaintiff's defective Philips System One CPAP device(s).

74. As a direct and proximate result of one or more of the above-stated actions, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT II

PRODUCT LIABILITY

MANUFACTURING DEFECT (NJSA 2A:58C-1, et seq.)

75. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

76. At all times, the use of the Recalled Devices, as well as Plaintiff's use of the Philips System One CPAP machine (and its components, such as the facemask), was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff, Mark Kramer, in the manner intended by Defendants.

77. The Recalled Devices, including the Philips System One CPAP machine used by Plaintiff, were defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendants, in that, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

78. Defendants, and each of them, knew or should have known of the defective nature of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, including (among other things), that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, and disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

79. The Defendants, and each of them, knew or should have known of the defective nature of the Recalled Devices, including the Plaintiff's System One machine, and the component parts of these BI-PAP and CPAP machines, including among other things, that the PE-PUR foam

used in the Recalled Device's component parts was prone to flaking, and disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

80. Specifically, the Defendants improperly designed the Recalled Devices, including the Plaintiff's System One machine, by:

a. Manufacturing certain Philips machines, including the Recalled Devices, including the Philips System One CPAP machine with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including laryngeal squamous cell carcinoma, as well as other injuries;

81. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT III

PRODUCT LIABILITY

FAILURE TO WARN (NJSA 2A:58C-1, et seq.)

82. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

83. The Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

a. the recalled machines, including the Philips System One CPAP device's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including laryngeal squamous cell carcinoma, as well as other injuries;

b. the recalled machines, including the Philips System One CPAP device's polyurethane PE-PUR sound abatement foam propensities to degradation and fragmentation;

c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and infiltrate the device's air pathway while the user is sleeping;

d. the risk of chronic inflammation resulting from use of the recalled machines, including the Philips System One CPAP device;

e. the risk of chronic infections resulting from the recalled machines, including the Philips System One CPAP device;

f. the risk of laryngeal, lung, kidney, and/or rectal cancers from exposure to the foam;

g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the Recalled Devices, including the Philips System One CPAP machine;

84. As a direct and proximate result of the recalled machines, including the Philips System One CPAP machine's aforementioned defects, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, obligations for medical services and expenses, and/or lost income, and other damages.

85. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling defective Philips System One CPAP machines.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT IV

FRAUDULENT MISREPRESENTATION

86. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

87. Philips failed to advise Plaintiff that the Recalled machines, including the Philips System One CPAP device used by Plaintiff, posed serious health risks to their users, and Philips falsely represented to Plaintiff that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, was safe for human use.

88. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and other members of the general public to purchase the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, Mark Kramer.

89. Philips knew that its representations and omissions about the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were false in that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, contained PE-PUR Foam and thus were at risk of causing adverse health effects to users including the Philips System One CPAP device used by Plaintiff.

90. The device does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff.

91. Plaintiff relied upon the representations of safety of the Philips System One and used the Philips System One CPAP device to his detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, Plaintiff's reliance on Philips' omissions and misrepresentations was justifiable.

92. As a direct and proximate result of the Recalled Devices, including the Philips System One CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V

FRAUD

93. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

94. Philips concealed from and failed to disclose to Plaintiff that use of Recalled Devices, including the Philips System One CPAP device used by Plaintiff, is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

95. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients, and suitability of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, for use by individuals; and (c) Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to obtaining the Philips System One CPAP device used by Plaintiff that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

96. The facts concealed or not disclosed by Philips to Plaintiff were material in that a reasonable consumer would have considered them important when deciding whether to obtain and use the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

97. Plaintiff justifiably relied on Philips' omissions to his detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

98. As a direct and proximate result of the recalled machines, including the Philips System One CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT VI

NEGLIGENT MISREPRESENTATION

99. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

100. Philips had a duty to Plaintiff, Mark Kramer, to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

101. Philips breached its duty to Plaintiff by developing, testing, manufacturing, advertising, marketing, and distributing products to Plaintiff that did not have the qualities, characteristics, and suitability for use as advertised by Philips, and by failing to promptly remove the Recalled machines, including the Philips System One CPAP device used by Plaintiff, from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

102. Philips knew or should have known that the qualities and characteristics of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were otherwise not as warranted and represented by Philips.

103. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT VII

BREACH OF EXPRESS WARRANTY

104. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

105. Philips marketed and sold the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, and placed them into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiff's insurer and other members of the general public.

106. Philips expressly warranted, advertised, and represented to Plaintiff and his insurer that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were safe and appropriate for human use.

107. Philips made these express warranties regarding the Recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Devices' packaging and labels. These express warranties became part of the basis of the bargain.

108. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were made in connection with the sale of the Recalled Device to Plaintiff's insurer. Plaintiff relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, in deciding whether to use Philips' Recalled Devices.

109. The Recalled Devices, including the Philips System One CPAP used by Plaintiff, do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

110. Philips therefore breached its express warranties by placing the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, into the stream of commerce and selling it to consumers, when their use posed health risks, and were dangerous and unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, and safety of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, rendering these devices worthless.

111. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, but Philips failed to warn Plaintiff he was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

112. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

113. The adverse health effects associated with use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, existed when they left Philips' possession or control and was obtained by Plaintiff. The dangers associated with use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were undiscoverable by Plaintiff when he received the Philips System One CPAP device.

114. As manufacturers, marketers, advertisers, distributors, and sellers of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, Philips had exclusive knowledge and notice of the fact that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, did not conform to the affirmations of fact and promises.

115. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff reasonably relied upon such representations and omissions in using the Philips System One CPAP device.

116. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiff.

117. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, was unsafe. Philips had ample opportunity either to stop using the PE- PUR Foam or to replace the PE-PUR Foam in the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, to make them safe and healthy for use by Plaintiff, but failed to undertake attempts to do so until now, and have still not repaired or replaced Plaintiffs and all impacted users machines.

118. As a direct and proximate result of the defects in the Recalled Devices, including the Philips System One CPAP device, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT VIII

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

119. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

120. Defendants are merchants engaging in the sale of goods to Plaintiff and members of the general public.

121. There was a direct sale of goods from Philips to Plaintiff's insurer which eventually became Plaintiff's property.

122. At all times mentioned herein, Philips manufactured or supplied the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, and prior to the time the Philips System One CPAP device used by Plaintiff was obtained by Plaintiff, Philips impliedly warranted to him that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were of merchantable quality, fit for its ordinary use, and conformed to the promises and affirmations of fact made on the Recalled Devices, including the Philips System One CPAP device used by Plaintiff'.

123. Plaintiff relied on Philips' promises and affirmations of fact when he obtained and used the Philips System One CPAP device.

124. Contrary to these representations and warranties, the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were not fit for its ordinary use and did not

conform to Philips' affirmations of fact and promises because use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

125. Philips breached its implied warranties with respect to the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices, including the Philips System One CPAP device used by Plaintiff, was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

126. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, through user reports submitted to Philips and through lab testing.

127. Privity exists because Philips impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices, including the Philips System One CPAP device used by Plaintiff, were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices, including the Philips System One CPAP device used by Plaintiff.

128. As a direct and proximate result of the Recalled Devices, including the Philips System One CPAP device's aforementioned defects, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff, Mark Kramer, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys fees, and such further relief as the Court deems equitable and just.

COUNT IX

VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT (NJSA 56:8-1, et seq.)

129. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

130. The subject product is considered "merchandise" as that term is defined by N.J.S.A. 56:8-l(c).

131. The Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of the subject CPAP device.

132. The Defendants knew, or should have known, that the subject device was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life-threatening injuries in its users.

133. Despite these facts, the Defendants omitted material facts in the disclosures it made to the public, the medical community, and to consumers, including Plaintiff herein, concerning the use and safety of the subject device.

134. Defendants have violated the New Jersey Consumer Fraud Act **(**N.J.S.A. 56:8-1 et seq.) in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including Plaintiff herein, concerning the use and safety of the subject device.

135. The Defendants' statements and omissions were made with the intent that the Plaintiff herein, and his health providers, would rely on such statements and omissions.

136. The Plaintiff obtained the subject device for personal use and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

137. The aforesaid promotion, statements, and/or omissions concerning the subject device by the Defendants constitute an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise of services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

138. As a direct and proximate result of the Defendants' acts of consumer fraud, Plaintiff, Mark Kramer, has suffered ascertainable loss - economic loss that includes the purchases of the subject device and additional out-of-pocket healthcare related costs - for which the Defendants are liable to Plaintiff for treble their actual damages.

COUNT X

LOSS OF CONSORTIUM

139. Plaintiffs repeat and reallege each of the foregoing allegations as though set forth at length herein.

140. Plaintiff, PEARL KRAMER, was and is the lawful spouse of Plaintiff, MARK F. KRAMER, and, as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

141. As a direct and proximate result of the foregoing, Plaintiff, PEARL KRAMER, was deprived of the comfort and enjoyment of the services and society of her spouse, Plaintiff, MARK F. KRAMER, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiffs MARK F. KRAMER's injuries and damages are permanent and will continue in the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

142. By reason of the foregoing, each Plaintiff has been damaged by the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows. For past and future general damages on each cause of action, according to proof:

1. For compensatory damage;

2. For past and future pain and suffering, according to proof;

3. For past and future loss of earnings and earning power, according to proof;

4. For reimbursement and future hospital, medical, nursing care, treatment, and incidental expenses, according to proof;

5. For past and future emotional distress, according to proof;

6. For punitive or statutory damages under the N.J. Consumer Fraud Act;

7. For past and future costs of suit incurred herein, and attorneys fees; and

8. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all issues so triable.

DATED: November 1, 2022

Respectfully submitted,

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